K112716

JAN 17 2012

GENOSS

510(k) Summary

12/26/2011

1. Company

	Submitter
Name	GENOSS Co., Ltd.
Address	1F Gyeonggi R&DB center, 906-5 Iui-dong, Suwon-si, Yeongtong-gu, Gyeonggi-do, 433-270, Korea
Phone/Fax	+82-31-888-5100/ +82-31-888-5105
Contact person	Sungwon Lee / QA swlee@genoss.com
Summary Date	September 14, 2011

2. Device Name

Proprietary name: OSTEON II
Common name: Bone grafting material
Classification name: Bone grafting material, Synthetic

3. Predicated Device

K062834 OSTEON

4. Description

This product is a synthetic osteoconductive bone graft substitute composed of hydroxyapatite (HA) and beta-tricalcium phosphate (β-TCP). This product presents an interconnected porous structure, similar to that of human cancellous bone. This product is available as irregular shaped particles of size 0.2~2.0 mm. It is supplied sterile by gamma irradiation.

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5. Indication for use

OSTEON II is intended for use as a bone grafting material to fill, augment or reconstruct periodontal or oral/maxillofacial defects.

- Periodontal/Infrabony defects
- Ridge augmentation
- Extraction sites (implant preparation/placement)
- Sinus lifts
- Cystic cavities

6. Technological Characteristics

OSTEON II has the similar technological characteristics as the predicate device; main material, indication for use and design. Technological characteristics of OSTEON II, OSTEON are as following

		Device name	
Material		**OSTEON**	**OSTEON II**
1	Hydroxyapatite(HA)	55~75wt%	25~45wt%
2	Beta-tricalciumphosphate(β-TCP)	25~45wt%	55~75wt%
Particles of size		0.3~2.0 mm	0.2~2.0mm
Indication for use		OSTEON (II) is intended for use as a bone grafting material to fill, augment or reconstruct periodontal or oral/maxillofacial defects. - Periodontal/Infrabony defects - Ridge augmentation - Extraction sites (implant preparation/placement) - Sinus lifts - Cystic cavities	
Sterilization		Gamma Irradiation	

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7. Performance Data

Biocompatibility testing on the proposed OSTEON II has been completed. Requirements for biological evaluation of the proposed device were based on the Blue Book memorandum G95-1 issued on May 1, 1995, Use of International Standard ISO10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing ." The biocompatibility test results show that the materials used in the design and manufacture of the components of the proposed device are non-toxic and non-sensitizing to biological bone and tissues with its intended use. The following biocompatibility tests were completed:

-ISO Cytotoxicity
-ISO Pyrogencity
-ISO Intracutaneous reactivity
-ISO Ames
-ISO Systemic toxicity
-ISO Sensitization
-ISO Implantation
-ISO Micro-nucleus

The proposed OSTEON II was evaluated using the following performance bench testing to confirm the performance characteristics:

-Ca/P ratio
-Porosity
-Density
-Crystalline Phase Compositions
-Water Solubility Test
-Crystallinity Value

All test results demonstrate that the materials chosen, the manufacturing process, and the design utilized for the OSTEON II met the established specifications necessary for consistent performance according to its intended use.

7. Conclusion

Based on the information provided in this premarket notification of GENOSS Co., Ltd. Concludes that OSTEON II is substantially equivalent to predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Republic of Korea 443-270

JAN 17 2012

Re: K112716
Trade/Device Name: OSTEON II
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: January 4, 2012
Received: January 5, 2012

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indication for use

510(k) Number:

Device Name: OSTEON II

Indication for use:

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Prescription Use ___√___ **AND/OR** **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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